

UNITED STATES DISTRICT COURT
for the
Southern District of Illinois

IN RE:)	
AMANDA KUHL and)	
JOSHUA KUHL,)	
Plaintiffs,)	
)	
vs.)	No. _____
)	
GEORGE SALIBA,)	
Defendant,)	

COMPLAINT AT LAW-WITH JURY DEMAND
Count I

Now comes the Plaintiff, Amanda Kuhl, by counsel and states as follows against the Defendant, George Saliba.

1. Jurisdiction of this matter is pursuant to diversity of citizenship, under 28 U.S.C. Section 1332(a)(1), in that the matter in controversy exceeds the sum or value of \$75,000.00 exclusive of interest and costs, and is between citizens of different states.

2. The Plaintiff Amanda Kuhl and the Plaintiff Joshua Kuhl are citizens and residents of Jasper County, State of Illinois. The Defendant, George Saliba, is a citizen and resident of the State of Indiana.

3. At all relevant times Joshua Kuhl was the lawful spouse and husband of Amanda Kuhl.

4. At all relevant times the Defendant, George Saliba, was a physician licensed to practice medicine in the State of Illinois, and practiced in the city of Newton, Jasper County, Illinois, in the field of internal medicine.

5. On or about February 21, 2014 the Defendant treated Amanda Kuhl for a plantar's wart

by attempting to remove the planter's wart with a 6-millimeter "punch" excision and thereafter, on or about April 23, 2014 removed additional tissue with a scalpel.

6. The condition of Amanda Kuhl after the care and treatment with the Defendant was such that she sought further care and treatment physicians and podiatrists, including Dr. Loesch and Dr. Parmenter, and has undergone additional care, treatment, and surgery as a result of the procedures preformed by the Defendant.

7. It was the duty of the Defendant, George Saliba, in rendering care and treatment to Amanda Kuhl to refrain from negligence and to render care and treatment that a reasonably careful internist would provide under like or similar circumstances.

8. In breach of the aforesaid duty, the Defendant, on the aforesaid dates committed one or more of the following negligent acts or omissions:

(a) Failed to treat the Plantar's Wart conservatively by deferring treatment to determine if the wart would resolve on its own;

(b) Failed to treat the Plantar's Wart conservatively with the administration of topical over-the-counter treatment or cryo (freezing) or with a laser;

(c) Failed to refer Amanda Kuhl to a podiatrist, rather than performing the surgical procedure as an internist.

9. The surgical procedure, performed by the Defendant, removed more tissue than was reasonable and necessary, and has caused Amanda Kuhl to undergo additional medical procedures as stated herein.

10. As a further direct, and proximate, result of one or more of the aforesaid negligent acts or omissions Amanda Kuhl has undergone additional surgical procedures, care, and treatment, and caused her disability, loss of a normal life, pain, suffering, emotional distress, disfigurement, and loss

of income and earning capacity, and loss of the chance for a better outcome all of which will continue.

11. The report pursuant to 735 ILCS 5/2-622, together with Affidavit are appended hereto and incorporated herein.

WHEREFORE, the Plaintiff prays this court award her damages against the Defendant in the sum of five million dollars (\$5,000,000.00) and cost of suit.

Count II

Now comes the Plaintiff, Joshua Kuhl, by counsel and states as follows against the Defendant.

1. Jurisdiction of this matter is pursuant to diversity of citizenship, under 28 U.S.C. Section 1332(a)(1), in that the matter in controversy exceeds the sum or value of \$75,000.00 exclusive of interest and costs, and is between citizens of different states.

2. The Plaintiff Amanda Kuhl and the Plaintiff Joshua Kuhl are citizens and residents of Jasper County, State of Illinois. The Defendant, George Saliba, is a citizen and resident of the State of Indiana.

3. At all relevant times Joshua Kuhl was the lawful spouse and husband of Amanda Kuhl.

4. At all relevant times the Defendant, George Saliba, was a physician licensed to practice medicine in the State of Illinois, and practiced in the city of Newton, Jasper County, Illinois, in the field of internal medicine.

5. On or about February 21, 2014 the Defendant treated Amanda Kuhl for a plantar's wart by attempting to remove the planter's wart with a 6-millimeter "punch" excision and thereafter, on

or about April 23, 2014 removed additional tissue with a scalpel.

6. The condition of Amanda Kuhl after the care and treatment with the Defendant was such that she sought further care and treatment physicians and podiatrists, including Dr. Loesch and Dr. Parmenter, and has undergone additional care, treatment, and surgery as a result of the procedures preformed by the Defendant.

7. It was the duty of the Defendant, George Saliba, in rendering care and treatment to Amanda Kuhl to refrain from negligence and to render care and treatment that a reasonably careful internist would provide under like or similar circumstances.

8. In breach of the aforesaid duty, the Defendant, on the aforesaid dates committed one or more of the following negligent acts or omissions:

- (a) Failed to treat the Plantar's Wart conservatively by deferring treatment to determine if the wart would resolve on its own;

- (b) Failed to treat the Plantar's Wart conservatively with the administration of topical over-the-counter treatment or cryo (freezing) or with a laser;

- (c) Failed to refer Amanda Kuhl to a podiatrist, rather than performing the surgical procedure as an internist.

9. The surgical procedure, performed by the Defendant, removed more tissue than was reasonable and necessary, and has caused Amanda Kuhl to undergo additional medical procedures as stated herein.

10. As a further direct, and proximate, result of one or more of the aforesaid negligent acts or omissions Amanda Kuhl has undergone additional surgical procedures, care, and treatment, and caused her disability, loss of a normal life, pain, suffering, emotional distress, disfigurement, and loss of income and earning capacity, and loss of the chance for a better outcome, all of which will


continue.

11. The report pursuant to 735 ILCS 5/2-622, together with Affidavit are appended hereto and incorporated herein.

12. As a further direct and proximate result of one or more of the aforesaid negligent acts or omissions, Joshua Kuhl has suffered a loss of consortium in that he has been deprived of the services of his wife, as well as her love, society and affection.

WHEREFORE, the Plaintiff, Joshua Kuhl, prays the court award damages against the Defendant in the sum of one-million dollars (\$1,000,000.00), together with cost of suit.

AMANDA KUHL and JOSHUA KUHL,
Plaintiffs,



Fred Johnson, Heller, Holmes & Associates,
P.C., Their Attorneys

FRED JOHNSON
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Mattoon, Illinois 61938
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JOSHUA KUHL,)	
Plaintiffs,)	
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vs.)	No. _____
)	
GEORGE SALIBA,)	
Defendant,)	

RULE 222 AFFIDAVIT

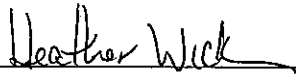
Now comes your affiant, Fred Johnson, and under oath, says:

- 1) That affiant is testifying to matters of affiant's own personal knowledge and is competent to testify to the same if called upon to do so.
- 2) That affiant is the duly authorized agent of Amanda Kuhl and Joshua Kuhl for purposes of making this affidavit.
- 3) That the damages sought do exceed \$50,000.00.

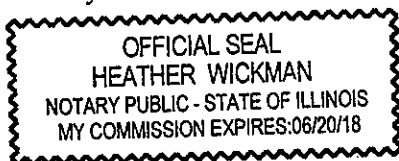


Of Heller, Holmes & Associates, P.C.

Subscribed and sworn to before me
this 14th day of September, 2015.



Notary Public



AFFIDAVIT

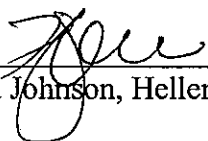
I, Fred Johnson, being duly sworn on oath depose and state as follows:

1. I reviewed the facts of the case with a health professional who I believe is knowledgeable in the relevant issues involved in the particular action, and practices or has practiced within the last six (6) years, or teaches or has taught within the last six (6) years, in the same area of healthcare or medicine that is at issue in the particular action, and is qualified by experience or demonstrated competence in the subject of the case.

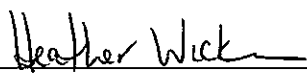
2. The reviewing health professional has determined in a written report, after review of the medical records and other relevant material, involved in the particular action that there is a reasonable and meritorious cause for the filing of the action.

3. The affiant has concluded, on the basis of the reviewing health professional's review and consultation that there is a reasonable and meritorious cause for the filing of such action.

FURTHER AFFIANT SAYTH NOT.


Fred Johnson, Heller, Holmes & Associates, P.C.

Subscribed and sworn to before me
this 14th day of September, 2015.


Notary Public



REPORT OF DR. ROBERT BUYNAK

I, Dr. Robert Buynak, am a physician licensed to practice medicine in all its branches, with a speciality in internal medicine. A copy of my curriculum vitae is attached to this report as Exhibit A. I have determined, after a review of the medical record and other relevant material involved, that there is a reasonable and meritorious cause for the filing of an action by Amanda Kuhl against Dr. George Saliba. I understand the Plaintiffs will be Amanda Kuhl and her husband Joshua Kuhl, and the Defendant will be Dr. George Saliba.

The reason for my determination, that a reasonable and meritorious cause for the filing of such action exists, is based upon my review of the record of care and treatment of Amanda Kuhl with Dr. George Saliba, at his office in Newton, IL, along with the record of her subsequent care and treatment with Dr. Richard Loesch and Dr. Parmenter. According to the record and materials I reviewed, Ms. Kuhl presented to Dr. Saliba, an internist, on February 20, 2014, for care and treatment of a Plantar's Wart.

According to the record, Dr. Saliba removed a 6-mm lesion with a 6-mm "punch" excision, on February 21, 2014. The specimen was not sent in for pathology. The patient again presented to Dr. Saliba on April 23, 2014, at which time the note of Dr. Saliba charts that: "symptoms include localized pain and frequent irritation." At that time, during an office visit, Dr. Saliba removed additional tissue described as a lesion "1 cm" in size. The removal was performed with a number 15 scalpel blade, and the wound left open to heal. On May 21, 2014, the patient again presented to Dr. Saliba at which time the record reflects "the area is tender with weight bearing."

Eventually, Ms. Kuhl sought treatment with Dr. Richard Loesch, a podiatrist. The records of Dr. Loesch, on June 24, 2014, document that the patient presented for an evaluation and

management of “scar tissue on the left foot, which was painful.” She continued to treat with Dr. Loesch. On September 30, 2014, the records of Dr. Loesch note that: “the patient returns today with a painful callus under her third MPJ of the left foot, which is the result of scar tissue from previous surgery. We removed the initial lesion with CO2 laser and it was reduced about fifty percent in size but is still very painful. I explained to her that I would like to consult a colleague of mine before planning further treatment. We then reduced the hyper-keratotic tissue in the area and she is to call toward the end of the week.”

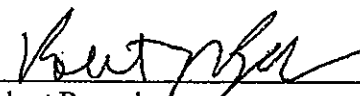
Further surgery was performed on December 2, 2014, by Dr. Loesch, at the Richland Memorial Hospital, at which time he performed a plantar condylectomy of the third metatarsal head and excision of scar tissue on the plantar aspect of the foot. The records of Dr. Loesch further indicate there was contracture dorsally at the metatarsal joint and he could palpitate a “lot of scar tissue over the dorsal aspect of the joint.” On February 25, 2015, the office note of Dr. Loesch reflects he spoke with Dr. Parmenter about the status of the third MPJ.

The basis of my finding and opinion, that a reasonable and meritorious cause for the filing of the action exists, is that no reasonably careful internist, under the circumstances the patient presented to Dr. Saliba, would have performed the surgical procedures he performed. Rather, Dr. Saliba should have treated the plantar wart conservatively either, with the patient’s option to wait and see if the wart resolved on its own or, alternatively, treated the wart topically with over-the-counter medication or with cryo (freezing), or with a laser, or referred the patient to a podiatrist for surgical consultation. Had alternative methods of treatment of the Plantar Wart, as referenced herein, been utilized it is more probably true than not that the wart would have resolved without the

need for surgical intervention. The invasive treatment of the wart, either with a "punch" excision or a scalpel, rather than with more conservative methods of treatment by an internist would pose an unnecessary risk of harm or injury to the patient such as occurred in the case of Amanda Kuhl. Simply stated, there is no reasonable explanation why alternative, more conservative, modalities of treatment should not have been undertaken by Dr. Saliba, rather than the "punch" excision and use of a scalpel to excise the wart.

The surgical procedure that was performed carried with it the unreasonable risk that the incision would cut too deeply, and cause damage to the foot of the patient, which would not occur with a more conservative approach. The surgical procedure should have been left to the determination of a podiatrist or other specialist, rather than an internist. The incisions made by Dr. Saliba removed too much tissue and resulted in the development of scar tissue and removal of a portion of the fatty layer of tissue, which in turn has necessitated her care and treatment with Dr. Loesch, and resulted in pain, suffering, and loss of a normal life to the patient. The procedure performed by Dr. Saliba was contraindicated and resulted in damage to Ms. Kuhl.

Date: 08/18, 2015.


Dr. Robert Buynak

Robert J. Buynak, MD, FACP
Board Certified, Internal Medicine
Lic. No. 01048425a

55 University Drive, Suite 106
Valparaiso, IN 46383
(219) 464-8302
Fax (219) 531-1825
rbuynak@att.net

CURRENT EMPLOYMENT

- | | |
|---|--------------------|
| - Private Practice, Internal Medicine | June 2005-Present |
| - Buynak Clinical Research
Principal Investigator | 2013-Present |
| - Northwest Indiana Center for
Clinical Research
Principal Investigator | Oct, 2004-Present |
| - Hilltop Community Health Center
Part-time, Internal Medicine | June 2005-Present |
| - Indiana University School of Medicine
Volunteer Clinical Instructor of Medicine | Sept, 1999-Present |

PREVIOUS EMPLOYMENT

- | | |
|--------------------------------|---------------------|
| - Portage Medical Group | July, 1998-May 2005 |
|--------------------------------|---------------------|

EDUCATION

- | | |
|---|-----------------------|
| Mayo Clinic
Internal Medicine Internship and Residency | July, 1995-July, 1998 |
| Harvard Medical School
Doctor of Medicine (MD) | Aug, 1991- May, 1995 |
| University of Notre Dame
Bachelor of Science, Biological Sciences | Aug, 1987-May 1991 |

HONORS and AWARDS

- Fellow, American College of Physicians (FACP) 2004
 - Chief of Medicine, Porter Hospital 2003
 - Porter County VNA Physician of the Year, 2004
 - Valedictorian, University of Notre Dame Class of 1991
 - Phi Beta Kappa, Alpha Epsilon Delta*
-

PUBLICATIONS

- Buynak RJ. Diabetes 1-2-3, A Simplified Guide to Managing Type 2 Diabetes, American Diabetes Association, Publication Date February 2006
- Buynak RJ. The Role of Primary Care in Bariatric Procedures. *Patient Care*, 2005: 39:7.
- Issue Editor, Special Focus on Neurology, *Patient Care*, 2002:7:4.
- Buynak RJ and Evans JM. Influenza in the Nursing Home: Prevention and Treatment. *Nursing Home Medicine* 1996; 4:319-324.
- Buynak RJ and Winter HS. Acquired Immunodeficiency Syndrome and Gastrointestinal Immune Function. *Curr Opin Gastroenterology* 1992; 8:1010-1014.
- El-Khalili N, Joyce M, Atkinson S, Buynak R, Datto C, Lindgren P, Eriksson H. Extended-release quetiapine fumarate (quetiapine XR) as adjunctive therapy in major depressive disorder (MDD) in patients with an inadequate response to ongoing antidepressant treatment: a multicentre, randomized, double-blind, placebo-controlled study. *Int Journal of Neuropsychopharm* (2010), 13, 917-932.
- Robert Buynak, Douglas Y Shapiro, Akiko Okamoto, Ilse Van Hove, Christine Rauschkolb, Achim Steup, Bernd Lange, Claudia Lange & Mila Etropolski. Efficacy and Safety of Tapentadol extended release for the management of chronic low back pain: results of a prospective, randomized, double-blind, placebo- and active-controlled Phase III study *Expert Opinion on Pharmacotherapy*, August 2010, Vol. 11, No. 11 , Pages 1787-1804

CLINICAL RESEARCH PROJECTS

- "Randomized, Open-Label, Multicenter Trial of the Safety and Effectiveness of Oral Telithromycin (Ketek) and Amoxicillin/Clavulanic Acid (Augmentin) in Outpatients With Respiratory Tract Infections in Usual Care Settings. Protocol # HMR3647A/3014. Aventis."
- A Multicenter, Open-Label, Crossover Study Comparing Maxalt (Rizatriptan Benzoate) with Usual Care Oral Migraine Medications. Protocol # SAIRB-02-0021. Merck."
- "REACH (REduction of Atherothrombosis for Continued Health) Registry, Sanofi."
- Impact of Point-of-Care Vs. Laboratory Testing of Hemoglobin A1C (HBA1C), and Intense Vs. Standard Monitoring of Titration Algorithm Adherence on Glycemic Control in Type 2 Diabetes Subjects, Who Are Inadequately Controlled on Oral Anti-Hyperglycemic Therapy, And Starting Lantus (Insulin Glargine Injection): A 2x2, Randomized, Open-Label Trial. Protocol # HOE-901-4033, Aventis."

-“TREAT (Trial to Reduce Cardiovascular Events with Aranesp Therapy) Protocol # 20010184 Amgen.”

-“JUPITER (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin) Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase III Study of Rosuvastatin (Crestor) 20mg in the Primary prevention of Cardiovascular Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein. Protocol # 4522US/0011 AstraZeneca.”

-“Randomized, Open-Label Study to Assess the Safety of Epoetin Alfa Manufactured by Deep Tank Technology and Epoetin Alfa Manufactured by Roller Bottle Technology in Subjects with Chronic Kidney Disease Not on Dialysis. Protocol # 20040259. Amgen.”

-“Randomized, Multicenter, Double-Blind, Placebo-Controlled, Single Dose Comparison of the Analgesic Activity of HKT-500 and Placebo in Subjects with Shoulder Pain. Protocol # HKT-500-US03. Hisamitsu.”

-“Randomized, Multicenter, Double-Blind, Placebo-Controlled, Two-Week Study to Assess the Safety and Efficacy of HKT-500 and Placebo in Subjects with Pain from Moderate Lateral Epicondylitis. Protocol # HKT-500-US-05.Hisamitsu.”

-“Randomized, Multicenter, Double-Blind, Placebo-Controlled, Two-Week Study to Assess the Safety and Efficacy of HKT-500 and Placebo in Subjects with Low Back Pain. Protocol # HKT-500-US-04.Hisamitsu.”

-“An Open-Label Safety Study with the Intermittent Use of HKT-500 in Subjects with Lower Back Pain, Pain from Osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain. Protocol # HKT-500-US-06.Hisamitsu.”

-“A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oravescent Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Neuropathic Pain. Protocol # C25608/3041/BP/US Cephalon.”

-“A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oravescent Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Low Back Pain. Protocol # C25608/3042/BP/US Cephalon.”

-“A Multi-centre, Double-blind, Randomized-withdrawal, Parallel-group, Placebo-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (SEROQUEL SR) as Monotherapy in the Maintenance Treatment of Patients with Major Depressive Disorder Following an Open-Label Stabilization Period (AMETHYST STUDY)”

-“ A Multicenter, Randomized, Double-Blind, Placebo Controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) In Combination with Thiazolidinedione Therapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Thiazolidinedione Therapy Alone” Protocol CV181013 Bristol-Myers Squibb

-“A double-blind, randomized study to evaluate the efficacy and safety of TAK-475 50 mg, 100 mg or placebo when co-administered with rosuvastatin (10 mg or 20 mg) in subjects with primary hypercholesterolemia.”

-“A randomized double-blind, double-dummy, placebo-controlled, 3x4 factorial design trial to evaluate telmisartan 20 and 80 mg tablets in combination with ramipril 1.25, 10, and 20 mg capsules after eight weeks of treatment in patients with State I or II hypertension, with an ABPM sub-study. Clinical Phase III.” Protocol # 1236.1 Boehringer Ingelheim

-“One Versus Two Versus Three Daily Rapid-Acting Insulin Injections of Apidra (Insulin Glulisine) As Add-On To Lantus and Oral Sensitizer Basal Therapy In Type 2 Diabetes: A Multi-Center, Randomized, Parallel, Open-Label Clinical Study. Protocol # HMR1964A/3511. Sanofi Aventis.”

-“A 13-week Multinational, Randomized, Double-Blind, Placebo-Controlled, Dose-Response Trial Assessing the Safety, Tolerability and Efficacy of AVE0010 In Metformin-Treated Subjects with Type 2 Diabetes Mellitus. Protocol # DRI6012. Sanofi Aventis.”

-“A Multi-Center, Double-Blind, Randomized-Withdrawal, Parallel-group, Placebo-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (Seroquel SR) as Monotherapy in the maintenance Treatment of Patients with Generalized Anxiety Disorder Following an Open-Label Stabilization Period (Platinum Study). Protocol # D1448C00012. AstraZeneca.”

-“A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained Release (Seroquel SR) in Combination with an Antidepressant in the Treatment of Patients with Major Depressive Disorder with Inadequate Response to an Antidepressant Treatment (Pearl Study). Protocol # D1448C00006. AstraZeneca.”

-“A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III, Efficacy & Safety Study of PTI-821 in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee.” Protocol #PTI-821-CO. Pain Therapeutics, Inc.”

-“A 4-Week Open-Label Study to Evaluate the Effect of Treatment With Fentanyl Buccal Tablets on Pain Anxiety Symptoms When used for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Pain.” Protocol #C25608/3054/BP/US. Cephalon, Inc.”

-“A Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Determine the Efficacy, Safety and Tolerability of AD-4833-536 in the Treatment of Subjects with Type 2 Diabetes and Hypertension.” Protocol No. 01-06-TL-OP1536-004. Takeda Global Research and Development Center, Inc.”

-“A Phase II, Double-Blind Randomized, Placebo-Controlled, Parallel Group, Multicenter Study to Evaluate Treatment with SYR619 in Subjects with Type 2 Diabetes.” Protocol #01-06-TL-SYR619-003. Takeda Global Research & Development Center, Inc.”

-“A Phase IIB, 12-Month, Double-Blind, Double-dummy, Randomized, Parallel-group, Multicentre Exacerbation Study of SYMBICORT pMDI 160/4.5 ug x 2 Actuations Twice-daily and 80/4.5 ug x 2 Actuations Twice-daily Compared to Formoterol TBH 4.5 ug x 2 Inhalations Twice-daily in COPD Subjects.” Protocol #DC589CC00003/Astra Zeneca.

-“A Phase 2 Randomized, Parallel Arm, Placebo-Controlled, Double Blind, Multiple-Dose Study of the Safety and Efficacy of RN624 in Adults with Moderate-to-Severe Pain due to Osteoarthritis of the Knee.” Protocol #RN624-CL006/Rinat Neuroscience Corporation.

-“ A Randomized, Double Blind, Placebo and Active Controlled, Parallel-arm, Phase III Study with Controlled Adjustment of Dose, Comparing the Efficacy and Safety of CG5503 Prolonged-Release (PR) and Oxycodone Controlled-Release (CR) to Placebo in Patients with Moderate to Severe Chronic Low Back Pain 9LBP.” Protocol R331333-PAI-3011/Johnson & Johnson.

-“A Randomized, Double-Blind, Placebo and Active Controlled, Parallel-arm, Phase III study with Controlled Adjustment of Dose, Comparing the Efficacy and Safety of CG5503 Prolonged-Release (PR) and Oxycodone Controlled Release (CR) to Placebo in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee.” Protocol R331333-PAI-3008/Johnson & Johnson.

-“A 52-week, randomized, double-blind, parallel-group, multi-centre, Phase IIIB study comparing the long term safety of SYMBICORT pMDI 160/4.5 ug x 2 actuations twice daily to budesonide HFA pMDI 160 ug x 2 actuations twice daily in adult and adolescent greater or equal to 12 years African American subjects with asthma.” Protocol D589C00022/Astra Zeneca.

-“Open-Label Extension, Single-Arm, Flexible-Dosing, Phase III Trial with CG5503 Extended-Release (ER) in Subjects with Moderate to Severe Chronic Pain. Protocol #331333-PAI-3010. Johnson & Johnson.

-“A Randomized-Withdrawal Phase III Study Evaluating the Safety and Efficacy of CG5503 Extended-Release (ER) in Subjects with Painful Diabetic Peripheral Neuropathy (DPN). Protocol #331333-PAI-3015. Johnson & Johnson.”

-“A Phase 3 Randomized, Double-Blind, Placebo and Active-Controlled, Multi-Center, Parallel Group Study to Evaluate the Safety and Efficacy of Darusentan In Subjects with Resistant Hypertension Receiving Combination Therapy with Three or more Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine or Placebo. Protocol#DAR-312. Gilead.”

-“A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Naltrexone 32 mg Sustained Release (SR)/Bupropion 360 mg Sustained Release (SR) and Placebo in Obese Subjects with Type 2 Diabetes Mellitus.”

-“A 12-week Open-label, Randomised, Parallel-group, Multicentre, Phase IIIB Study to Compare the Efficacy and Safety of Rosuvastatin (CRESTOR) 10 g and 20 mg in Combination with Ezetimibe 10 mg (fixed dose combination) in Patients with Hypercholesterolaemia and Coronary Heart Disease 9CHD) or a CHD Risk Equivalent, Atherosclerosis or a 10-year CHD Risk of >20%.”

•**BIAsp2192 (NovoNordisk)(Initiate Plus):** Randomized, Open-Label, Trial of the efficacy of safety of a standard titration algorithm coupled with conventional dietary intervention or intensive dietary intervention versus a standard titration algorithm, alone, in patients with type 2 diabetes initiating Novolog Mix 70/30 therapy

- **C25608/3040/BP/US (Cephalon):** An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Noncancer Pain
- **RN624-CL007 (Rinat Neuroscience Corporation):** An Open-Label, Multiple-Dose Study of the Safety and Efficacy of RN624 in Adults with Pain Due to Osteoarthritis of the Knee
- **01-05-TL-491-008 (Takeda):** A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of TAK-491 in Subjects with Essential Hypertension
- **TAK-491-CLD_306 (Takeda):** A Phase 3, Double-Blind, Randomized, Efficacy and Safety Study of the TAK-491 Plus Chlorthalidone Fixed-Dose Combination Compared With TAK-491 and Hydrochlorothiazide Coadministration Therapy in Subjects With Moderate to Severe Essential Hypertension
- **M10-277 (Abbott):** A Phase 3, Open-Label Period Followed by a Randomized, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy of Extended-Release Hydrocodone/Acetaminophen (Vicodin CR™) Compared to Placebo in Subjects With Chronic Low Back Pain
- **EFC6016 (GETGOAL-L)(sanofi aventis):** A randomized, double-blind, placebo-controlled, 2-arm parallel-group, multicenter study with a 24-week main treatment period and an extension assessing the efficacy and safety of AVE0010 in patients with Type 2 diabetes insufficiently controlled with basal insulin
- **MB102-030 (Bristol-Myers Squibb & AstraZeneca):** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Combination with Thiazolidinedione Therapy in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Thiazolidinedione Therapy Alone
- **NB-303 (Orexigen Therapeutics, Inc.):** A Multicenter, Randomized, Double-blind, Placebo Controlled Study Comparing the Safety and Efficacy of Naltrexone Sustained Release (SR)/Bupropion Sustained Release (SR) and Placebo in Obese Subjects
- **D1441L00016 (AstraZeneca):** A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of Quetiapine Fumarate Extended-Release (Seroquel XR) Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine
- **GI-5005-02 (GlobelImmune, Inc.):** A Phase 2 Randomized, Open Label, Multi-center, Therapeutic Trial of the Efficacy, Immunogenicity, and Safety of GI-5005; an Inactivated Recombinant *Saccharomyces cerevisiae* Expressing a Hepatitis C Virus NS3-Core Fusion Protein, Combined with Pegylated Interferon plus Ribavirin Standard of Care Therapy versus Standard of Care Alone, and GI-5005 Salvage of Standard of Care Failures, in Patients with Genotype 1 Chronic Hepatitis C Infection

●**NMT 1077-301 (Neuromed Pharmaceuticals, Inc.):** A Phase III, Variable-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Chronic Low Back Pain

●**D1448C00010 (GOLD)(AstraZeneca):** A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-controlled Study of the Efficacy and Safety of Sustained-release Quetiapine Fumarate (SEROQUEL®) Compared with Placebo in the Treatment of Generalized Anxiety Disorder (Gold Study)

●**A4091015 (Pfizer):** A Phase 3 Randomized, Double-Blind Placebo and Naproxen Controlled Multicenter Study of the Analgesic Efficacy and Safety of Tanezumab in Patients with Osteoarthritis of the Knee

●**42160443-PAI-2003 (Johnson & Johnson):** A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Dose-Loading Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42160443 as Adjunctive Therapy in Subjects With Inadequately Controlled, Moderate to Severe, Chronic Low Back Pain

●**42160443-PAI-2004 (Johnson & Johnson)(2009-2011):** A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42160443 as Adjunctive Therapy in Subjects With Moderate to Severe Knee or Hip Pain From Osteoarthritis

●**Lu AA21004_309 (ALLIANCE)(Takeda):** A Randomized Double-blind, Parallel-group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of 2 Doses of Lu AA21004 in Acute Treatment of Adults With Generalized Anxiety Disorder

●**28431754DIA3009 (CANTATA-SU)(Johnson & Johnson):** A Randomized, Double-Blind, 3-Arm Parallel-Group, 2-Year (104-Week), Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-28431754 100 mg and JNJ-28431754 300 mg Compared With Glimepiride in the Treatment of Subjects With Type 2 Diabetes Mellitus Not Optimally Controlled on Metformin Monotherapy

●**Lu AA21004_315 (Takeda)(2010-2011):** A Phase 3, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Duloxetine-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses (15 and 20 mg) of Lu AA21004 in Acute Treatment of Adults With Major Depressive Disorder

●**Lu AA21004_314 (Takeda)(2010-2011):** A Phase 3, Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of Lu AA21004 (15 and 20 mg) in Subjects With Major Depressive Disorder

●**D4130C00007 (Renaissance)(AstraZeneca)(2010-2011):** A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase III, Long-Term Safety and Tolerability Study of TC-5214 (S-mecamylamine) as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder Who Exhibit an Inadequate response to Antidepressant Therapy

●**28431754DIA20003 (Johnson & Johnson):** A Randomized, Double-blind, Placebo-controlled, 3-Arm, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Monotherapy

●**HYD3003 (Purdue Pharma L.P.):** An Open-label, Multicenter Study to Assess the Long-term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects With Moderate to Severe Chronic Nonmalignant and Nonneuropathic Pain

●**TAK-875_202 (Takeda):** A Phase 2, Randomized, Placebo-controlled, Factorial, Double-blind, Double-dummy, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of 25 mg and 50 mg of TAK-875 in Combination with Sitagliptin 100 mg in Subjects With Type 2 Diabetes Mellitus

●**MK-0653C (Merck):** A Randomized, Double-blind, Active-controlled, Multicenter, Crossover Study to Evaluate the Efficacy of Ezetimibe/Atorvastatin 10 mg/40 mg Fixed Dosed Combination Tablet Compared to Co-administration of Marketed Ezetimibe 10 mg and Atorvastatin 40 mg in Patients With Primary Hypercholesterolemia

●**GLP114179 (GlaxoSmithKline):** A Randomized, Open-label, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide as compared With Liraglutide in Subjects With Type 2 Diabetes

●**GLP114130 (GlaxoSmithKline):** A Randomized, Double-blind, Active-controlled, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide as Compared With Sitagliptin in Subjects With Type 2 Diabetes Mellitus With Renal Impairment

●**1220.48 (Boehringer Ingelheim):** A Phase III, Open-label Study of Once Daily BI 201335 240 mg for 24 Weeks in Combination With Pegylated Interferon-a (PegIFN) and Ribavirin (RVB) in Patients With Genotype 1 Chronic Hepatitis C Infection who Failed a Prior PegIFN / RBV Treatment

●**1220.47 (Boehringer Ingelheim):** A Phase III, Randomized, Double-blind and Placebo-controlled Study of Once Daily BI 201335 240 mg for 12 Weeks in combination With Pegylated Interferon-a and Ribavirin in Treatment-Naïve Patients With Genotype 1 Chronic Hepatitis C Infection

●**1220.7 (Boehringer Ingelheim):** A Phase III, Randomized, Double-blind and Placebo Controlled Study of Once Daily BI 201335, 240 mg for 12 or 24 Weeks in combination With Pegylated Interferon-a and Ribavirin in Patients With Genotype 1 Chronic Hepatitis C Infection who Failed a Prior PEGIFN/RBV Treatment

●**HCZ113782 (GlaxoSmithKline):** A Clinical Outcomes Study to Compare the Effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg With Placebo on Survival in Subjects With Moderate Chronic Obstructive Pulmonary Disease (COPD) and a History of or at Increased Risk for Cardiovascular Disease

●**BAY 98-7106/14725 (Bayer):** A Multicenter, Multifactorial, Randomized, Double-blind, Placebo-controlled Dose-finding Study of Nifedipine GITS and Candesartan in Combination Compared to Monotherapy in Adult Patients with Essential Hypertension

●**42160443PAI2003 (Johnson & Johnson):** A Randomized, Double-blind, Placebo-Controlled, Dose-ranging, Dose-loading Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-42160443 as Adjunctive Therapy in Subjects With Inadequately Controlled, Moderate to Severe, Chronic Low Back Pain

●**42160443PAI2004 (Johnson & Johnson):** A Randomized, Double-blind, Placebo-controlled, Dose-ranging Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-42160443 as Adjunctive Therapy in Subjects With Moderate to Severe Knee or Hip Pain From Osteoarthritis

●**TMX-67_301 (Takeda):** A Multicenter, Randomized, Active-control, Phase 3B Study to Evaluate the Cardiovascular Safety of Febuxostat and Allopurinol in Subjects With Gout and Cardiovascular Comorbidities

●**TMX-67_203 (Takeda):** A Multicenter, Randomized, Double-blind, Phase 2 Study to Evaluate the Effect of Febuxostat Versus Placebo on Renal Function in Gout Subjects With Hyperuricemia and Moderate to Severe Renal Impairment

●**D4130C00004 (FIXED)(AstraZeneca):** A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase III, Efficacy and Safety Study of 3 Fixed Dose Groups of TC-5214 (S-mecamylamine) as an Adjunct to an Antidepressant in Patients With Major Depressive Disorder Who Exhibit an Inadequate Response to Antidepressant Therapy

●**ONU3701 (Purdue Pharma L.P.):** A Randomized, Double-blind, Placebo-controlled Multicenter Trial With an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-Release Tablets (OXN) Compared to Placebo in Opioid-Experienced Subjects With Moderate to Severe Pain Due to Chronic Low Back Pain who Require Around-the-Clock Opioid Therapy

●**A3191172 (PRECISION)(Pfizer):** A Randomized, Double-blind, Parallel-group of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing Celecoxib With Naproxen and Ibuprofen

●**M12-807 (Abbott):** A Phase 2, Randomized Withdrawal Study of the Analgesic Efficacy and Safety of Hydrocodone/Acetaminophen Extended Release Compared to Placebo in Subjects With Chronic Low Back Pain

●**SPD489-329 (Shire):** A Phase 3, Open-label, Multicenter, 12-Month Extension Safety and Tolerability Study of SPD489 in Combination With an Antidepressant in the Treatment of Adults With Major Depressive Disorder With Residual Symptoms or Inadequate Response Following Treatment With an Antidepressant

●**SPD489-322 (Shire):** The SPD489-322 Phase 3, Multicenter, Randomized, Double-blind Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination With an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant

●**GI-5005-02 (Globelimmune, Inc.):** A Phase 2 Randomized, Open Label, Multi-center, Therapeutic Trial of the Efficacy, Immunogenicity, and Safety of GI-5005; an Inactivated Recombinant *Saccharomyces cerevisiae* Expressing a Hepatitis C Virus NS3-Core Fusion Protein, Combined with Pegylated Interferon plus Ribavirin Standard of Care Therapy versus Standard of Care Alone, and GI-5005 Salvage of Standard of Care Failures, in Patients with Genotype 1 Chronic Hepatitis C Infection

●**CNVA 237A2303 (Novartis):** A 52-Week Treatment, Randomized, Double-blind, Placebo-controlled, With Open Label Tiotropium, Parallel-group Study to Assess the Efficacy, Safety and Tolerability of NVA237 in Patients With Chronic Obstructive Pulmonary Disease

●**A4091014 (Pfizer):** A Phase 3, Randomized, Double-blind, Placebo-controlled Multicenter Study of the Analgesic Efficacy and Safety of Tanezumab in Patients With Osteoarthritis of the Hip

●**TAK-491CLD_303 (Takeda):** A Phase 3b, Double-blind, Randomized, 12-Week Efficacy and Safety Study Comparing the TAK-491 Plus Chlorthalidone Fixed-dose Combination vs Olmesartan Medoxomil-Hydrochlorothiazide in Subjects With Moderate to Severe Hypertension

●**EFC10007 (Allegro):** A Randomized, Double-blind, Parallel-group, Multicenter, Multinational Study to Assess Glycemic Control With Rimonabant in Comparison with Glimepiride Over 1 Year in Overweight/Obese Type 2 Diabetic Patients Not Adequately Controlled with Metformin

●**DAR-312 (DORADO-AC)(Gilead Sciences, Inc.):** A Phase 3 Randomized, Double-Blind, Placebo- and Active- Controlled, Multi-center, Parallel Group Study to Evaluate the Safety and Efficacy of Darusentan in Subjects with Resistant Hypertension Receiving Combination Therapy with Three or More Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine or Placebo

●**D0520C00012 (BREEZE)(AstraZeneca):** A 12-Week, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multinational, Phase 11b Dose Range Finding Study to Evaluate the Efficacy and Safety of AZD9668 Administered Orally at 3 Dose Levels to Patients With Chronic Obstructive Pulmonary Disease (COPD) on Treatment With Tiotropium

●**M10-889 (Abbott):** A Global Multicenter, Randomized, Double-blind, Placebo-and Active-controlled Study Comparing the Analgesic Efficacy and Safety of ABT-652 to Placebo in Subjects With Osteoarthritis Pain of the Knee

●**LuAA21004_303 (Takeda):** A Randomized, Double-blind, Parallel-Group, Placebo-controlled, Fixed-dose Study Comparing the Efficacy and Safety of LuAA21004 Versus Placebo in Acute Treatment of Adults With Major Depressive Disorder

●**A4091016 (Pfizer):** A Phase 3, Multicenter, Randomized, Long Term Study of the Safety of Tanezumab in Patients With Osteoarthritis of the Knee or Hip

●**NB-CVOT (Orexigen):** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Occurrence of Major Adverse Cardiovascular Events (MACE) in Overweight and Obese Subjects With Cardiovascular Risk factors receiving Naltrexone SR/Bupropion SR

●**1245.25 (Boehringer Ingelheim):** A Phase III , Multicenter, International, Randomized, Parallel Group, Double-Blind Cardiovascular Safety Study of BI 10773 (10mg and 25mg Administered Orally Once Daily) Compared to Usual Care in Type 2 Diabetes Mellitus Patients with Increased CardiovascF3

●**HPP404-201 (High Point):** A 26 Week Randomized, Double-Blind, Placebo-Controlled Phase 2 Study to Evaluate the Safety and Efficacy of Various Doses of HPP404 on Weight Loss in Overweight or Obese Subjects

●**HYD3002 (Purdue):** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study With an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-Daily in Subjects With Moderate to Severe Chronic Low Back Pain

●**1241.21 (Boehringer Ingelheim):** Safety, Antiviral Effect and Pharmacokinetics of BI 207127 in Combination With BI 201335 and With or Without Ribavirin for 4, 16, 24, 28, or 40 Weeks in Patients With Chronic HCV Genotype 1 Infection (Randomized Phase Ib/II)

●**VDN2001 (Purdue):** A phase 2, Randomized, Double-Blind, Placebo-and Active-Controlled, Parallel-Group, Multicenter Study Evaluating the Analgesic Efficacy and Safety of V116517 in Subjects With Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

●**CP-OXYDET-08 (Collegium):** A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of Oxycodone DETERx Versus Placebo in Opioid-Experienced and Opioid-Naïve Subjects with Moderate-to-Severe Chronic Low Back Pain

●**MK-3102-018 (OMNEON-18) (Merck):** A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess Cardiovascular Outcomes Following Treatment with MK-3102 in Subjects with Type 2 Diabetes Mellitus

●**1241.36 (Boehringer Ingleheim):** A Phase III Randomized, Partially Double-blind and Placebo-controlled Study of BI 207127 in Combination with Faldaprevir and Ribavirin for Chronic Genotype 1 Hepatitis C Infection in an Extended Population of Treatment Naïve Patients that Includes those Ineligible to Receive Peginterferon

●**BC28027 (ALEPREVENT) (Roche):** A Phase 3B Study to Evaluate the Potential of Alegitazar to Reduce Cardiovascular Risk in Patients with Stable Cardiovascular Disease and Glucose Abnormalities

●**14801 (DISTINCT)(Bayer):** A Multicenter, Open-Label, Long-Term Safety and Efficacy Study of the Fixed Dose Combination of Nifedipine Gastrointestinal Therapeutic System and Candesartan Cilexetil in Subjects with Moderate to Severe Essential Hypertension

●**GRT-MD-101(Forest):** A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Safety and Efficacy of GRT6005 in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

●**ITCA 650-CLP-103 (INTARCIA):** a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of ITCA 650 in Patients with Type 2 Diabetes

●**ITCA 650-CLP-103-Sub-study (INTARCIA):** An Open-Label Multi-Center Sub-Study to Evaluate the Efficacy, Safety and Tolerability of ITCA 650 in Patients with Type 2 Diabetes with High Baseline HbA1c

●**ITCA 650-CLP-107 (INTARCIA):** A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with ITCA 650 in Patients with Standard of Care for Type 2 Diabetes

●**ITCA 650-CLP-105 (INTARCIA):** A Phase 3, Randomized, Active Comparator, Double-Blind Study to Compare the Efficacy, Safety and Tolerability of ITCA 650 to Sitagliptin as Add-on-Therapy to Metformin in Patients with Type 2 Diabetes

●**1326V9235 (SHIONOGI):** A Randomized Double-blind, Placebo-controlled, Parallel-group, Multicenter Phase 3 Study to Evaluate the Long-term Safety of Naldemedine for the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy

●**1218.22 (CAREMELINA) (Boehringer Ingelheim):** A Multicenter, International, Randomized, Parallel group, Double-blind, Placebo-controlled Cardiovascular Safety and Renal Microvascular outcome with LINAgliptin 5mg once daily in Patients with Type 2 Diabetes Mellitus at High Vascular Risk

●**B1481020 (Pfizer):** A Phase 3 Double-blind, Placebo-controlled, Parallel-group Study to Assess the Efficacy, Long-term Safety and Tolerability of PF-04950615 in Subjects with Primary Hyperlipidemia or Mixed Dyslipidemia at Risk of Cardiovascular Event

●**B1481022 (Pfizer):** A Phase 3 Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Evaluation of the Efficacy, Safety and Tolerability of PF-04950615 in Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects

●**B1481038 (Pfizer):** A Phase 3 Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Evaluation of the Efficacy, Safety, and Tolerability of PF-04950615, in Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects

●**LAS-MD-45 (Forest):** A Double-blind, Randomized, Placebo-controlled, Parallel-group, Phase IV Study to Evaluate the Effect of Acridinium Bromide on Long-term Cardiovascular Safety and COPD Exacerbations in Patients with Moderate to Very Severe COPD

●**EFC12404 (Sanofi):** A Randomized, 30 week, Active-Controlled, Open-Label, 3-Treatment Arm, Parallel-Group Multicenter Study Comparing the Efficacy and Safety of Insulin Glargine/Lixisenatide Fixed Ratio Combination to Insulin Glargine alone and to Lixisenatide Alone on Top of Metformin in Patients with Type 2 Diabetes Mellitus

●**DIA4003 (Janssen):** A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects with Type 2 Diabetes Mellitus

●**HCZ113782 (GlaxoSmithKline):** A Clinical Outcomes Study to Compare the Effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg With Placebo on Survival in Subjects With Moderate Chronic Obstructive Pulmonary Disease (COPD) and a History of or at Increased Risk for Cardiovascular Disease

●**D3251C00003 (GALATHEA) (Astra Zeneca):** A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicentre, Phase III Study to Evaluate the Efficacy and Safety of 2 Doses of Benralizumab (MEDI-563) in Patients with Severe to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with a History of COPD Exacerbations (GALATHEA)

●**ALK5461-205 (Alkermes):** A Phase 3 Efficacy and Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-4 Study)

●**15Q-MC-CGAF (CHORUS):** A Phase 2, Randomized, Double-Blind, Placebo and Active-Controlled Trial of LY29151742 in Patients with Mild to Moderate Osteoarthritis Pain of the Knee

●**D589UC0001 (RISE) (Astra-Zeneca):** A Phase IIIB, 6-Month, Double-Blind, Double-Dummy, Randomized Parallel-Group, Multicenter Exacerbation Study of Symbicort pMDI 160/4.5 ug x 2 Inhalations Twice-Daily in COPD Patients

●**14-AVP-786-201 (Avanir):** A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled study to Assess the Efficacy, Safety, and Tolerability of AVP-786 (Deuterium Modified Dextromethorphan Hydrobromide/Quinidine Sulfate) as an Adjunctive Therapy in Patient with Major Depressive Disorder with and Inadequate Response to Anti-depressant Treatment

●**SUN-101-303 (Sunovion):** A Randomized, Open-label, Active-controlled, Parallel-group, Multicenter, Long-term Safety Trial of Treatment with Nebulized Sun-101 in Patients with COPD: Golden-5 (Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer)

●**D5881C0004 (STRENGTH) (Astra-Zeneca):** A Long-term Outcomes Study to Assess Statin Residual Risk Reduction with Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia

●**SUN-101-302 (Sunovion):** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Efficacy and Safety Trial of 12 Weeks of Treatment with Nebulized SUN-101 in Patients with COPD: Golden-4 (Glycopyrrolate for Obstructive Lung Disease Via Electronic Nebulizer)